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Introduction

This bibliography lists the publications (Pharmacoepidemiological and Clinical Publications, Congress Proceedings, Posters, Clinical Guidelines and Institutional Documents) produced using Cegedim Strategic Data (CSD) databases.

CSD is part of the Cegedim Group. CSD is a leading market and medical research company (including CRO activities) with over 40 years of experience in the healthcare industry.

CSD’s product portfolio, scientific expertise and network of market researchers, analysts, statisticians, doctors, epidemiologists and pharmacists enable it to provide truly integrated healthcare research. CSD offers a comprehensive range of market and medical research solutions to meet the needs of its customers.

CSD Medical Research provides international healthcare data and studies to researchers, governments, universities and the pharmaceutical industry.

To conduct its studies CSD Medical Research uses real-world evidence from:

- Longitudinal Patient Databases (LPD): patient and prescription information collected through a constant panel of office-based primary and secondary care physicians equipped with Cegedim’s Electronic Medical Records (EMR) software. Over 70 million active patients are continuously tracked with LPD. Anonymised clinical data are transmitted daily to CSD’s Longitudinal Patient Database servers. CSD has longitudinal patient databases in Australia, Belgium, France, Germany, Italy, Spain, UK, and USA.

- INES© online study management and e-CRF.

In each section, citations are classified and sorted using the latest version of the International Classification of Diseases (ICD-10) recommended by the World Health Organization (WHO).

The different types of publications are represented by the following symbols:

- Pharmacoepidemiological and Clinical Publications
- Congress Proceedings
- Posters
- Clinical Guidelines and Institutional Documents

For publications not in English, the language is specified in square brackets.
## Congress and Association Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Name</th>
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<tbody>
<tr>
<td>ADELF</td>
<td>Association Des Epidémiologistes de Langue Française</td>
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<tr>
<td>AFSSAPS</td>
<td>Agence Française de Sécurité Sanitaire des Produits de Santé</td>
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<tr>
<td>APA</td>
<td>American Psychiatric Association</td>
</tr>
<tr>
<td>ASBMR</td>
<td>American Society for Bone and Mineral Research</td>
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<tr>
<td>ASCO</td>
<td>American Society of Clinical Oncology</td>
</tr>
<tr>
<td>ASH</td>
<td>American Society of Hematology</td>
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<tr>
<td>ASN</td>
<td>American Society of Nephrology</td>
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<tr>
<td>CPLF</td>
<td>Congrès de Pneumologie de Langue Française</td>
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<tr>
<td>EAHP</td>
<td>European Association of Hospital Pharmacists</td>
</tr>
<tr>
<td>EAU</td>
<td>European Association of Urology</td>
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<tr>
<td>ECTS</td>
<td>European Calcified Tissue Society</td>
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<td>EGS</td>
<td>European Glaucoma Society</td>
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<td>EHA</td>
<td>European Hematology Association</td>
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<td>ERS</td>
<td>European Respiratory Society</td>
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<tr>
<td>ESC</td>
<td>European Society of Cardiology</td>
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<td>ESH</td>
<td>European Society of Hypertension</td>
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<td>European Society for Medical Oncology</td>
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<td>ESSM</td>
<td>European Society for Sexual Medicine</td>
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<td>EULAR</td>
<td>European League Against Rheumatism</td>
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<tr>
<td>EuroDURG</td>
<td>European Drug Utilisation Research Group</td>
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<td>HAS</td>
<td>Haute Autorité de Santé</td>
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<td>IBMS</td>
<td>International Bone and Mineral Society</td>
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<tr>
<td>ICPE</td>
<td>International Conference on Pharmacoepidemiology &amp; Therapeutic Risk Management</td>
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<tr>
<td>ICS</td>
<td>International Continence Society</td>
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<tr>
<td>IHEA</td>
<td>International Health Economics Association</td>
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<td>INVS</td>
<td>Institut National de Veille Sanitaire</td>
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<td>IPA</td>
<td>International Psychogeriatric Association</td>
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<td>ISPE</td>
<td>International Society for Pharmacoepidemiology</td>
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<tr>
<td>ISPOR</td>
<td>International Society for Pharmacoconomics and Outcomes Research</td>
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<tr>
<td>JNI</td>
<td>Journées Nationales d’Infectiologie</td>
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<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<td>PCCS</td>
<td>Primary Care Cardiovascular Society</td>
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<tr>
<td>SAPC</td>
<td>Society for Academic Primary Care</td>
</tr>
<tr>
<td>SEESP-SEM</td>
<td>Service Evaluation Economique et Santé Publique – Service Evaluation des Médicaments</td>
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<tr>
<td>SFC</td>
<td>Société Française de Cardiologie</td>
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<tr>
<td>SFD</td>
<td>Société Francophone de Dialyse</td>
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<tr>
<td>SFGM-TC</td>
<td>Société Française de Greffe de Moelle et de Thérapie Cellulaire</td>
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<td>SFH</td>
<td>Société Française d’Hématologie</td>
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<td>SIHTA</td>
<td>Società Italiana di Health Technology Assessment</td>
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<td>SRLF</td>
<td>Société de Réanimation de Langue Française</td>
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<tr>
<td>UFR</td>
<td>Unités de Formation et de Recherche</td>
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</table>
A00-B99: Certain infectious and parasitic diseases

2014


2013


2012


2011


2010


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2008


2007


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C00-D48: Neoplasms

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2008

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2007

Analyse des pathologies et de la prise en charge thérapeutique des patients en France. HAS: 2007. [French]●


2006


2005


Poster Examples
ADHERENCE TO TREATMENT AND PERSISTENCY IN PATIENTS TREATED WITH VKA IN FRANCE, ITALY, GERMANY, SPAIN AND UK

INTRODUCTION

Atrial fibrillation (AF) is a frequently-occurring cardiac arrhythmia with an estimated prevalence in the general population of Europe and North America of between 1% and 2% [1-3]. Prevalence increases with age, from less than <0.5% between 40 and 50 years, to 5-15% over 80 years [4], the incidence doubling for each 5-year age group. Part of the morbidity and mortality associated with AF can be attributed to increased vulnerability to stroke. Atrial fibrillation increases the risk of ischemic stroke by nearly five-fold [5] and accounts for around one in five of all strokes [6]. In addition, AF-related strokes are associated with a higher recurrence rate and higher mortality [7].

In order to prevent the occurrence of stroke in patients with AF, prophylaxis with oral anticoagulants is recommended [8]. Historically, warfarin (or vitamin K antagonists) have been the mainstay of oral anticoagulation, but more recently new oral anticoagulants (NOACs: direct oral anticoagulants) which are simpler to use and potentially safer and more effective, are available [9]. The American College of Chest Physicians (ACCP) [10] recommends using the CHADS2 score [11] to stratify treatment risk and that all patients with a CHADS2 score 2 or above in long-term prophylaxis with an oral anticoagulant. Guidelines from the European Society of Cardiology (ESC) acknowledge the CHADS2 risk score but recommend NOACs be preferred in the absence of monitoring requirements for coumadin time and a lower risk of bleeding. However, this has not yet been demonstrated in everyday practice. We have recently performed a large survey (REACT-AF) of the use of oral anticoagulants in PS patients with AF in five European countries. This study provides an opportunity to collect data on adherence to oral anticoagulants in everyday practice.

OBJECTIVES

The overall goal of the REACT AF study was to investigate management and outcomes associated with stroke prophylaxis in patients with non-valvular AF (NVAF) in Europe. The primary objective was to determine treatment persistence with oral anticoagulants and antiplatelet therapy prescribed for stroke prevention in patients with NVAF. The present analysis provides the data on persistence and adherence observed in patients treated with VKA.

METHODS

Context:
A retrospective observational cohort study of patients with NVAF conducted in five European countries (France, Germany, Italy, Spain and the United Kingdom) between May 2010 and May 2012.

Data source:
• Data were extracted from electronic medical records in the Cegedim Strategic Data Longitudinal Patient Database (LPD).
• All eligible patients consulting during the study period were enrolled.

Patient eligibility:
• Aged ≥ 18 years
• Diagnosis of NVAF at any time before study end
• Consulted at least once during 2-year study period
• Medical record documented for ≥1 year before index consultation
• ≥ 1 follow-up consultation since index consultation
• Absence of rheumatic valvular diseases or prosthetic valves

Treatment groups:
Four groups were defined on the basis of treatment documented in the database
• No treatment group: no treatment with VKA, NOAC or antiplatelet drugs
• APA group: treatment with antiplatelet drugs (including aspirin) only
• VKA group: treatment with a VKA ± antiplatelet drugs
• NOACs group: treatment with a NOAC ± antiplatelet drugs

Determination of stroke risk:
Stroke risk was determined using the CHADS2/CHA2DS2-VASc score at the time of AF diagnosis or when treatment was initiated [12].

Determination of persistence:
• Treatment persistence was determined from prescription dates.
• The date of treatment initiation was defined as the first date of prescription of any treatment of the same class in the entire patient record documented in the LPD.
• Discontinuation of treatment was defined as a gap of three months between two consecutive dates of prescription.
• Persistence duration was estimated as the time to treatment discontinuation, calculated from the date of treatment initiation to the date of the last prescription before discontinuation using Kaplan-Meier survival analysis.

Determination of adherence:
• Adherence to treatment was estimated by treatment class using the Medication Possession Ratio (MPR).
• The total duration of the index consultation was used as the last use before the use cut-off of 30th April 2012 was divided by the number of times the patient consulted in the two-year time period.
• An MPR ≥ 0.80 was considered to represent good adherence.

RESULTS

Patients included:
Overall, 85,423 patients were included from the five participating countries (Figure 1). Of these, 10,011 (46.4%) were prescribed a VKA. Only 86% (10,101) were prescribed a NOAC.

DISCUSSION

Over half the patients in the study had interrupted their VKA treatment for at least six months, exposing them to a risk of stroke.

Median treatment duration before interrupting treatment for at least three months was less than two years. Between two-thirds and three-quarters of patients presented an inadequate level of treatment adherence, defined as an MPR <0.80. The MPR was close to 0.5, indicating that VKA medication was not used on one day out of two across the 2-year study period.

The findings were consistent between countries, which suggest that the problem is inherent to the medication class and not related to the health system.

The findings of the REACT-AF study highlight the poor adherence to anticoagulant prophylaxis with VKAs in everyday care of patients with NVAF in different European countries. This puts these patients at increased risk of stroke and unsatisfactory outcomes. Management strategies and patient education are needed to improve adherence to VKAs and thus reduce the risk of stroke in the NVAF population.

REFERENCES

Table 1. Demographic characteristics and stroke risk of included patients at the index consultation by country.

<table>
<thead>
<tr>
<th>Country</th>
<th>France (N = 5 184)</th>
<th>Germany (N = 3 388)</th>
<th>Spain (N = 7 526)</th>
<th>United Kingdom (N = 7 526)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (%)</td>
<td>5 104 (68.8% )</td>
<td>2 200 (65.5% )</td>
<td>5 994 (80.7% )</td>
<td>7 103 (84.1% )</td>
</tr>
<tr>
<td>Female (%)</td>
<td>2 480 (31.2% )</td>
<td>1 188 (34.5% )</td>
<td>1 532 (19.3% )</td>
<td>4 423 (15.9% )</td>
</tr>
<tr>
<td>CHA2DS2-VASc score</td>
<td>2.7 [0 - 9]</td>
<td>2.2 [0 - 9]</td>
<td>2.1 [0 - 9]</td>
<td>2.2 [0 - 9]</td>
</tr>
<tr>
<td>CHADS2 score</td>
<td>2.7 [0 - 9]</td>
<td>2.2 [0 - 9]</td>
<td>2.1 [0 - 9]</td>
<td>2.2 [0 - 9]</td>
</tr>
<tr>
<td>No treatment group: no treatment with VKA, NOAC or antiplatelet drugs</td>
<td>3 297 (42.6% )</td>
<td>1 527 (45.3% )</td>
<td>6 235 (82.8% )</td>
<td>7 057 (80.4% )</td>
</tr>
<tr>
<td>APA group: treatment with antiplatelet drugs (including aspirin) only</td>
<td>5 154 (68.4% )</td>
<td>2 634 (74.7% )</td>
<td>1 644 (25.2% )</td>
<td>634 (7.6% )</td>
</tr>
<tr>
<td>VKA group: treatment with a VKA ± antiplatelet drugs</td>
<td>3 517 (46.5% )</td>
<td>1 053 (31.0% )</td>
<td>515 (8.0% )</td>
<td>150 (1.9% )</td>
</tr>
<tr>
<td>NOACs group: treatment with a NOAC ± antiplatelet drugs</td>
<td>2 926 (37.5% )</td>
<td>590 (17.3% )</td>
<td>200 (3.0% )</td>
<td>20 (0.2% )</td>
</tr>
</tbody>
</table>

Table 2. Median treatment duration.

<table>
<thead>
<tr>
<th>Country</th>
<th>France</th>
<th>Italy</th>
<th>Spain</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>APA group: treatment with antiplatelet drugs (including aspirin) only</td>
<td>1.34 [1.28; 1.42]</td>
<td>0.85 [0.81; 0.92]</td>
<td>1.00 [0.95; 1.05]</td>
<td>1.92 [1.84; 2.02]</td>
</tr>
<tr>
<td>VKA group: treatment with a VKA ± antiplatelet drugs</td>
<td>1.00 [0.95; 1.05]</td>
<td>0.90 [0.85; 0.95]</td>
<td>1.05 [1.00; 1.10]</td>
<td>1.15 [1.10; 1.20]</td>
</tr>
<tr>
<td>NOACs group: treatment with a NOAC ± antiplatelet drugs</td>
<td>0.85 [0.81; 0.92]</td>
<td>0.75 [0.70; 0.80]</td>
<td>0.90 [0.85; 0.95]</td>
<td>0.95 [0.90; 1.00]</td>
</tr>
</tbody>
</table>

Table 3. Median treatment duration.

<table>
<thead>
<tr>
<th>Country</th>
<th>France (N = 5 184)</th>
<th>Germany (N = 3 388)</th>
<th>Spain (N = 7 526)</th>
<th>United Kingdom (N = 7 526)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antiplatlet agents</td>
<td>3.0 [0 - 9]</td>
<td>3.0 [0 - 9]</td>
<td>3.0 [0 - 9]</td>
<td>3.0 [0 - 9]</td>
</tr>
<tr>
<td>VKA antithrombotic agents</td>
<td>2.7 [0 - 9]</td>
<td>2.2 [0 - 9]</td>
<td>2.1 [0 - 9]</td>
<td>2.2 [0 - 9]</td>
</tr>
</tbody>
</table>

Table 4. Proportion of patients still under treatment as a function of treatment duration.
Assessing the completeness of maternity data in UK primary and secondary care: a study in The Health Improvement Network (THIN) and Hospital Episode Statistics (HES)

S Man1,2 I Petersen2 I Nazareth2 A Bourke1 M Thompson1
1 Cegedim Strategic Data 2 University College London, Dept Primary Care & Population Health

Most pregnant women in the UK are seen by General Practitioners (GP) for antenatal services, but deliver their babies in secondary care. Hence, linked primary and secondary care records, potentially, offer a rich data source for research on pregnancy and birth.

The aim of this study was to compare the completeness of maternity data from primary care using The Health Improvement Network (THIN) with secondary care data from Hospital Episodes Statistics (HES).

METHODS

- This preliminary comparison uses a linked dataset of 15,166 patients identified in ONE GP practice.
- Patients are linked to their HES records by their NHS number using encrypted key technology from a trusted third party.

RESULTS

<table>
<thead>
<tr>
<th>% of pregnancies with complete data</th>
<th>Of 3,255 pregnancies in HES</th>
<th>Of 2,649 pregnancies in THIN using ONLY mothers records</th>
<th>Of 1,212 pregnancies in THIN ONLY where there is a linked child</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>74.8</td>
<td>98.9</td>
<td>94.8</td>
</tr>
<tr>
<td>Social deprivation</td>
<td>43.6</td>
<td>99.9</td>
<td>99.9</td>
</tr>
<tr>
<td>Number of previous pregnancies</td>
<td>80.0</td>
<td>60.8</td>
<td>60.9</td>
</tr>
<tr>
<td>Mode of delivery</td>
<td>22.5</td>
<td>28.8</td>
<td>34.8</td>
</tr>
<tr>
<td>Number of babies</td>
<td>12.5</td>
<td>13.9</td>
<td>6.0</td>
</tr>
<tr>
<td>Gestational age</td>
<td>5.1</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td>Birthweight</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Sex</td>
<td>6.0</td>
<td>6.0</td>
<td>6.0</td>
</tr>
</tbody>
</table>

CONCLUSIONS

- Data on ethnicity, mode of delivery, number of babies and birth weight are better recorded in HES than THIN.
- However, THIN can provide more information than HES on number of previous pregnancies, gestational age, and sex of the baby when pregnancies can be linked to a child.
- Birth details (e.g. birth weight, gestational age and sex) in HES are better recorded than presented in our results, however we were unable to use a large proportion of the data due to lack of linkage within HES to the mother’s delivery record.
- Both HES and THIN have advantages therefore there are gains to be made from combining HES and THIN data.

Further work is needed to...

- Analyse the completeness of these variables using combined THIN-HES data.
- Verify the preliminary results by extending the analysis to all THIN-HES linked practices.
- Investigate the unexpected differences in recording e.g. number of pregnancies.

Funded by an MRC Industrial CASE studentship awarded to Shuk-Li Man. For further information, please email shuk-li.man.10@ucl.ac.uk

Scan for online copy of poster (requires QR code scanner)
What impact has NICE clinical guideline 69 had on the diagnosis of, and antibiotic prescribing for, upper respiratory tract infections? A THIN database study

Richard J. List BMedSci BMBS MRCS DOHNS, Tina Sedani BSc, Michelle Johnson GradStat MSc BSc, Gianluca Lucrezi BSc

University of Sheffield, Sheffield, UK Cegedim Strategic Data Medical Research Ltd, London, UK

THE PROBLEM

Antibiotics prescribed in primary care for respiratory tract infections in adults and children account for 60% of all antibiotic prescribing in the UK and constitute a significant cost to the NHS. However, international comparisons have shown that lower rates of antibiotic prescribing are not associated with higher rates of complications.

Unnecessary prescribing of antibiotics has the potential to cause drug-related adverse events, to increase the prevalence of antibiotic-resistant organisms in the community and to increase primary care consultation rates for minor illness.

In the UK, National Institute for Health and Clinical Excellence (NICE) clinical guideline 69 was published during 2008 with the intention of reducing unnecessary antibiotic prescribing for self-limiting upper respiratory tract infections (URTIs). This was to be achieved by the use of clinical assessment to identify non-severe cases and adoption of a no prescribing strategy or delayed prescribing strategy (dispensed if symptoms failed to resolve or worsened).

The effect of this guideline on diagnosis and antibiotic prescribing has not previously been reported.

THE APPROACH

The Health Improvement Network (THIN) database contains electronic primary care patient records from 559 general practices across the UK. This database was used to identify patients presenting to primary care in the UK with a recorded diagnosis of acute URTI (excluding bronchitis). Of these patients, those with a record of an associated antibiotic prescription were then identified.

Comparison was made between those diagnosed before (March 2005 to February 2008 inclusive) and after (March 2008 to February 2011) the guideline was published.

FINDINGS

On average, 380,479 patients (8.8%, mean N=4,302,446) were diagnosed with acute URTI each year (between 2005 and 2011). The yearly percentage of patients with a recorded diagnosis of acute URTI ranged from 8.4% in 2009-10 (March 2009 to February 2010 inclusive) to 9.2% in 2007-08 (Figure 1). Comparison between time periods before and after guideline publication revealed a small decrease in the mean percentage of patients with acute URTI from 9.1% in 2005-08 to 8.7% in 2008-11 (difference in the percentage -0.40, 95% CI -0.44 to -0.36, Table 1).

Of the diagnosed patients, 191,589 patients (50.4%) received an antibiotic prescription on average each year (between 2005 and 2011). The yearly percentage with an antibiotic prescription ranged from 46.8% in 2009-10 to 57.7% in 2010-11 (Figure 2). The mean percentage with an antibiotic prescription was 49.9% in 2005-08 compared to 50.8% in 2008-11 (difference in the percentage 0.85, 95% CI 0.63 to 1.08, Table 2).

Table 1: Comparison of acute upper respiratory tract infection (URTI) patients with an antibiotic prescription before and after guideline publication

<table>
<thead>
<tr>
<th>Year</th>
<th>Before guideline</th>
<th>After guideline</th>
<th>Difference in % (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005-06</td>
<td>4,221,575</td>
<td>381,917</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
<tr>
<td>2006-07</td>
<td>4,383,316</td>
<td>379,041</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
<tr>
<td>2007-08</td>
<td>4,367,655</td>
<td>379,041</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
<tr>
<td>2008-09</td>
<td>4,302,446</td>
<td>379,041</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
<tr>
<td>2009-10</td>
<td>4,256,397</td>
<td>379,041</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
<tr>
<td>2010-11</td>
<td>4,205,289</td>
<td>379,041</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
</tbody>
</table>

Table 2: Comparison of acute upper respiratory tract infection (URTI) patients with an antibiotic prescription before and after guideline publication

<table>
<thead>
<tr>
<th>Year</th>
<th>Before guideline</th>
<th>After guideline</th>
<th>Difference in % (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005-06</td>
<td>381,917</td>
<td>190,694</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
<tr>
<td>2006-07</td>
<td>379,041</td>
<td>192,484</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
<tr>
<td>2007-08</td>
<td>379,041</td>
<td>192,484</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
<tr>
<td>2008-09</td>
<td>379,041</td>
<td>192,484</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
<tr>
<td>2009-10</td>
<td>379,041</td>
<td>192,484</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
<tr>
<td>2010-11</td>
<td>379,041</td>
<td>192,484</td>
<td>-0.40 (-0.44 to -0.36)</td>
</tr>
</tbody>
</table>

CONSEQUENCES

• Overall, 8.8% of patients in THIN were diagnosed with acute URTI each year.
• There was evidence to suggest a very small reduction in the recording of a diagnosis of acute URTI following the introduction of the NICE guideline.
• On average, 50.4% of diagnosed patients received an antibiotic prescription each year.
• Contrary to expectations, there was no evidence of a reduction in antibiotic prescribing following the publication of the NICE guideline.
• Furthermore, there was some evidence of an increase in the proportion prescribed antibiotics, although the difference was very small and may not be clinically relevant.

Future research could investigate whether there has been a change in criteria for recording a diagnosis of URTI and whether there have been longer term changes in the incidence of URTI and associated antibiotic prescribing.
The Atrial Fibrillation Longitudinal Outcomes Assessment (AFLOAT) study was funded by Sanofi.

Cause of death (COD) recording in UK general practices is dependent on several factors including reporting to the general practitioner, relevance and expectedness of the information, medico-legal influences and local recording practices. The AFLOAT study assessed health outcomes, including death, among patients with atrial fibrillation (AF; N=9,418) and matched control patients (N=47,090) aged ≥ 40 years in The Health Improvement Network (THIN) primary care dataset. Within two years of follow-up, 9.6% (N=5,428) of the study population had died. The AFLOAT study used death certificates to supplement COD information, however the COD information recorded in THIN prior to this was also investigated.

To assess the distribution of COD recording in THIN among the AFLOAT study population.

COD was sourced from coded and free-text information in THIN. COD was assessed over two years of follow-up plus an additional four months to allow for retrospective administrative recording of death. COD recording was assessed across cohorts, genders, age groups and practice sizes. Differences in proportions of recorded COD were investigated using the chi-squared test (all characteristics) and chi-squared test for trend (age group and practice size).

From coded and free-text information, COD was available for 45.6% (N=2,474) of patients who died. There was no evidence at the 5% level to suggest that the amount of COD recording differed between cases and controls (p=0.642) or males and females (p=0.602, Table). However, there was evidence that recording differed across age groups (p=0.012); the proportion of patients with COD recorded in each age group ranged from 41.3% (60-69 years) to 47.8% (80-89 years). COD was recorded more frequently in the older age groups (p=0.018 [trend test], Figure 1).

The proportion of patients with COD recorded in each practice size category ranged from 41.3% (small practices; 1,000 to 8,000 patients) to 49.0% (large practices; 12,000 to 30,000 patients; Table). There was evidence that the amount of COD recording differed across practice sizes (p<0.001) and was recorded more frequently in the larger practices (p<0.001 [trend test], Figure 2).

It is possible to access death certificates through THIN and this would supplement COD information from within the data alone.

OBJECTIVES

METHODS

RESULTS

CONCLUSIONS

- Approximately half of the AFLOAT study patients who died during the two year follow-up period had a recorded COD in THIN.
- COD was recorded more frequently in the older age groups (>80 years) and larger practices.
- When designing and interpreting study information utilising COD data, potential for bias should be assessed.

It is possible to access death certificates through THIN and this would supplement COD information from within the data alone.
1. INTRODUCTION

SMBG is one of the core components of diabetes therapy – irrespectively of the therapeutic approach (diet only, oral medications or insulin). It supports a safe and effective drug therapy and provides additional feedback on how diet and lifestyle impact blood glucose levels. Accordingly it is recommended by both international diabetes therapy guidelines and national guidelines (e.g. ADA guideline). The necessary testing frequency is based on the specific therapeutic approach as well as the individual ability of patients to make best use of SMBG information for therapy and lifestyle adjustments. Drugs that can cause hypoglycemia (e.g. sulfonylureas, insulin) do require SMBG for safety reasons. Furthermore, any insulin therapy with a flexible insulin dosing scheme does require frequent SMBG for adequate insulin dose determination to support a safe and effective therapy.

SMBG is reimbursed in many healthcare systems – in particular in combination with insulin therapy. Individual affordability of SMBG, e.g. in case of non-reimbursement or co-payments, impairs the adherence to recommended test frequencies. And SMBG test frequencies correlate with the quality of glycemic control.

2. OBJECTIVES

In 2011, a Chinese guideline on SMBG was published. SMBG in contrast to most diabetes drugs is not reimbursed in China. This study aims to assess the level of SMBG usage in patients on different diabetes therapies. It also explores the correlation of SMBG usage with glycemic control.

3. METHODS

1st half year 2011 data (10,418 cases) from the CDS PDS Diabetes survey were used for this explorative analysis. PDS Diabetes is a syndicated research with a fixed representative panel of 180 endocrinologists and 120 cardiologists from 13 large Chinese cities. Patient cases are documented in a given standardized format. SMBG usage was analyzed by therapy-subgroups: oral anti-diabetic therapy only (OAD), insulin (single or multiple daily injections, NPH insulin or premixed insulin), conventional insulin therapy (CT), no OAD use, basal oral therapy (BOT), in IIT patients differences in HbA1c were observed. The patient group tested at the recommended test frequency of at least 3 times per week. For patients on a conventional insulin therapy the same test frequency is recommended in the stable phase. This is achieved by 11.4% of these patients. For the IIT group the CDS guideline recommends 2-4 tests per day in the maintenance phase. 3% of IIT treated patients included into this study tested at the recommended test frequency.

Table 1: Patient demographics

<table>
<thead>
<tr>
<th>Type 1</th>
<th>Type 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes type</td>
<td></td>
</tr>
<tr>
<td>OAD</td>
<td>50.6%</td>
</tr>
<tr>
<td>BOT</td>
<td>24.8%</td>
</tr>
<tr>
<td>CT</td>
<td>14.9%</td>
</tr>
<tr>
<td>IIT</td>
<td>11.7%</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
</tr>
<tr>
<td>&lt;60</td>
<td>47.9%</td>
</tr>
<tr>
<td>60 - 90</td>
<td>22.3%</td>
</tr>
<tr>
<td>&gt;90</td>
<td>26.8%</td>
</tr>
<tr>
<td>Not reported</td>
<td>1.0%</td>
</tr>
<tr>
<td>Diagnosed since (years)</td>
<td></td>
</tr>
<tr>
<td>&lt;5</td>
<td>33.9%</td>
</tr>
<tr>
<td>5 - 14</td>
<td>41.3%</td>
</tr>
<tr>
<td>&gt;15</td>
<td>24.8%</td>
</tr>
<tr>
<td>Not reported</td>
<td>0.0%</td>
</tr>
<tr>
<td>SMBG</td>
<td></td>
</tr>
<tr>
<td>&lt;24</td>
<td>50.9%</td>
</tr>
<tr>
<td>24 - 28</td>
<td>27.1%</td>
</tr>
<tr>
<td>&gt;28</td>
<td>0.0%</td>
</tr>
<tr>
<td>Not reported</td>
<td>0.4%</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td></td>
</tr>
<tr>
<td>&lt;=6.5</td>
<td>14.3%</td>
</tr>
<tr>
<td>&gt;6.5 to 8</td>
<td>44.9%</td>
</tr>
<tr>
<td>&gt;8</td>
<td>34.8%</td>
</tr>
<tr>
<td>Not reported</td>
<td>0.0%</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>27.0%</td>
</tr>
<tr>
<td>Obesity</td>
<td>21.4%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>30.5%</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>24.8%</td>
</tr>
</tbody>
</table>

5,288 patients (50.8%) had a meter for SMBG home-testing. Figure 1 provides the share of testers by therapy group.

Figure 1: Share of patients that perform SMBG at home (OTHERS excluded)

A high share of patients included in this study did not have a meter to perform SMBG at home. For testers with BOT, CT and IIT test frequencies remained clearly below the Chinese guideline recommending 10, 10, and 21 test per week in the initiation phase and respectively 6, 6, and 14-28 tests per week in the stable phase. For IIT where SMBG is essentially needed to support insulin dose adjustments only 1% of the analyzed patient group tested at the ADA guideline-recommended frequency of at least 21 tests per week. In IIT patient differences in HbA1c were largest between testers and non-testers. Further research is needed to clarify if e.g. education or reimbursement could potentially resolve these shortfalls.

4. RESULTS

Patient demographics are listed in Table 1. Overall 16.0% had no comorbidities, while 21.2%, 25.1%, 18.9%, and 18.8% had 1, 2, 3, or >3 comorbidities. Patients with type 1 diabetes had an above 29% prevalence for hypertension, hyperlipidemia and retinopathy; for type 2 patients these were hypertension, hyperlipidemia and obesity.

For patients using basal insulin the guideline recommends 3 tests per week when therapy goals are achieved. 22.7% of BOT treated patients tested at least 3 times per week. For patients on a conventional insulin therapy the same test frequency is recommended in the stable phase. This is achieved by 11.4% of these patients. For the IIT group the CDS guideline recommends 2-4 tests per day in the maintenance phase. 3% of IIT treated patients included into this study tested at the recommended test frequency.

Figure 2 shows the HbA1c levels by different therapy segments and bG meter availability. HbA1c levels were by 0.2%, 0.5%, 0.4%, and 1.2% lower in SMBG users in the OAD, BOT, CT and IIT segment.

5. CONCLUSIONS

References

**Clinical Attributes, Treatments, and Control In Hypertension (CATCH) Study - France**

**Authors:** David Wu Ph.D, David Drouot M.D., Vasalisaz Sazonov Ph.D

**Global Health Outcomes Meets & Co., Inc., Whistler Station, Stn 2, U.S.**

| Department Medical Research, Cogmedys Strategic Data (CSD), Paris, France |

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### BACKGROUND

- Cardiovascular disease (CVD) causes 15 times the number of deaths and 11 times the direct economic burden compared to HIV/AIDS, tuberculosis, and malaria in Europe. Hypertension is one of the main modifiable risk factors for CVD, affecting 60% of the adult population in Europe.3

- Although hypertension is traditionally focused on blood pressure (BP) control, research is needed regarding the morbidity and mortality associated with the disease.4

- European guidelines emphasize that the diagnosis and management of hypertension should be based on individual clinical risk factors.5

- Furthermore, specific therapeutic approaches and BP targets are not always clearly defined in clinical practice.6

- Despite several improvement in BP treatment and control over the past decades in Europe, many patients are still not achieving their BP goal, which indicates that the level of current awareness and satisfaction may vary across patient groups.7

- To help better understand remaining unmet needs and gaps in BP treatment, and to inform future guidelines, we conducted this large retrospective study on medical records from 40,000 randomly selected hypertensive patients treated in actual clinical practices in Italy.8

### STUDY OBJECTIVES

1. To identify demographic characteristics and cardiovascular risk profiles of patients with hypertension for the complete clinical period of follow-up (April 2007 - December 2008)

2. To examine and document hypertension pharmacological treatment patterns, changes in medications and medication adherence (patients not at risk for renal disease were included in the data analysis).

3. To assess blood pressure goal attainment in clinical study population as well as outside with additional data collection and assess associated demographic and clinical factors for goal attainment.

### STUDY METHODOLOGY

**Study design**

- Retrospective, observational, longitudinal cohort study on extracted data from proprietary longitudinal patient databases in Italy.

- Study inclusion criteria:

  - Hypertensive patients aged ≥18 years at index date
  - BP measurement at index date
  - No increase in dose of antihypertensive medication

- Index date (April 1, 2007) - index treatment

- Follow-up period: 12 months

- Data were extracted from electronic medical record (EMR) databases that contain patient-level demographics, diagnoses, prescriptions, and other medical data electronically collected by participating general clinical practices across Italy, consistent with the clinical setting where the data were collected.

### StudY RESULTS

**Distribution of Patient Segments**

<table>
<thead>
<tr>
<th>Patient Segment</th>
<th>Total number of eligible patients</th>
<th>n=147,964</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Patient Demographics and Clinical Profile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BP Goal Attainment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distribution of Patient Segments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline Population</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Patterns in Isolated Systolic Hypertension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changes in Treatment From Index Medications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment-Related Adverse Events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changes in Treatment From Index Medications</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Data analysis**

- Definition of patient segments

- Baseline hypertension demographics and clinical profile

- BP goal attainment

- Distribution of patient segments

- Treatment patterns in isolated systolic hypertension

- Distribution of patient segments

**Conclusion/Discontinuation**

- A majority (86%) of French hypertensive patients managed by general clinical practice areunnecessarily hypertensive with other CVD comorbidity conditions.

- After one year of treatment, compliant HTN patients were less likely to achieve BP control compared with their non-compliant HTN counterparts. A majority of compliant HTN patients (81%) did achieve clinical BP goals.

- Among treatment-naive patients, ARB was the most prescribed first-line therapy (86%) followed by CCB (10%) and ACEI (4%).

- Among prior treated patients, few combination therapy was the most prescribed initial therapy (43%) followed by ARB (31%), ACEI (15%), and CCB (11%).

- CV risk conditions, baseline BP and older age were significant factors associated with not achieving BP goal attainment after controlling for other covariables.

**STUDY LIMITATION**

- The study results are subject to the quality and availability of the EMR data collected by the participating general clinical practices.

- Findings may not be generalizable to the population given the limitations of the clinical settings where the data were collected.
Initially developed in English language, the tool has been minor modifications were made to the MMAS to make it more suitable for measuring medication adherence in patients treated with oral medications for osteoporosis (OS-MMAS).

The Morisky Medication Adherence Scale (MMAS) is a simple tool that has been validated in chronic conditions such as hypertension.

The construct validity of the tool was assessed using the intraclass correlation coefficient (ICC), the Bland Altman test and the paired t-test.

The validity of the tool was assessed using confirmatory factor analysis (CFA).

The reproducibility of the tool was evaluated using the intraclass correlation coefficient (ICC), the Bland Altman test and the paired t-test.

The construct validity of the tool was assessed using confirmatory factor analysis (CFA).

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INTRODUCTION

Major depressive disorder (MDD) is one of the most prevalent psychiatric disorders, leading to substantial suffering of the patients, a heavy burden for the family and significant socioeconomic consequences in terms of costs. MDD affects around 150 million adults worldwide and in Italy the number of people with this disease is estimated to be about 5 million, with a lifetime prevalence between 8 and 13%. [1]

The World Health Organization ranked MDD as the first leading cause of years lost due to disability worldwide and the third cause of disability worldwide projecting that by 2030 it will be the first leading cause. [2] MDD constitutes an important burden both in terms of direct costs (e.g., treatments, hospitalizations), which represent 31% of the total costs, and also indirect costs (low productivity, comorbidities or death), which account for 62% of the overall costs of Depression. [3, 4]

Kind and Sorensen showed that pharmaceutical treatments accounted for 11.3% of the total costs of MDD. [5, 6] An estimation of the economic burden of MDD was $93.1 billion worldwide in 2004. The main treatments used in MDD include antidepressant drugs, psychotherapy, and somatic treatment. Selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) are two of the most effective classes of antidepressants with a higher safety profile than the tricyclic antidepressants (TCAs). [7] SSRIs are also cost-effective in comparison with the older antidepressants in long-term treatment of MDD. [7, 8]

OBJECTIVE

The objective of this study, called C-QUALITY (Cost and Quality of Life Pharmacoeconomic Analysis on MDD) in Italy, was to assess the cost-effectiveness of SSRIs and SNRIs used in first-line treatment of MDD, adopting the Italian National Health Service perspective.

METHODS

An analytic decision model was adapted from the one developed by the Swedish Dental and Pharmaceutical Benefits agency (TLV) to simulate the management of Italian patients with MDD, with the help of an expert panel, composed of eight psychiatrists and two health economists. The model (Figure 1) evaluated patients with a first diagnosis of MDD receiving an SSRI or an SNRI for the first time.

Efficacy and utility data for the model were retrieved from the literature and validated by the expert panel. Local data were considered for resource utilization and for treatment costs based on each regional health service perspective. Population-based weighted regional data were used to feed the national model. Scenarios simulations, one-way sensitivity analyses, and Probabilistic Sensitivity Analysis using Monte Carlo simulations were performed to test the robustness of the model.

RESULTS

Cost-Utility Analysis (CUA) in the base case showed that, despite its relatively high acquisition cost, the SSRI escitalopram is associated with a lower total cost (€ 1,562.4) compared with all other treatment strategies, reflecting the fact that on average patients spend less time in the costly depression state.

Furthermore, escitalopram is associated with a larger health gain (QALYs) at 1 year (0.732) and, therefore, dominates the other treatment strategies as more QALYs are achieved at a lower total cost. (Table 1)

Table 1. Base Case Results

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Cost (€)</th>
<th>QALYs</th>
<th>ICER (€/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escitalopram</td>
<td>1,562.4</td>
<td>0.732</td>
<td>2,178.6</td>
</tr>
<tr>
<td>Sertraline</td>
<td>1,579.5</td>
<td>0.724</td>
<td>Dominated</td>
</tr>
<tr>
<td>Venlafaxine</td>
<td>1,601.6</td>
<td>0.729</td>
<td>Dominated</td>
</tr>
<tr>
<td>Paroxetine</td>
<td>1,598.1</td>
<td>0.724</td>
<td>Dominated</td>
</tr>
<tr>
<td>Citalopram</td>
<td>1,625.3</td>
<td>0.720</td>
<td>Dominated</td>
</tr>
<tr>
<td>Fluoxetine</td>
<td>1,630.0</td>
<td>0.719</td>
<td>Dominated</td>
</tr>
<tr>
<td>Duloxetine</td>
<td>1,649.2</td>
<td>0.727</td>
<td>Dominated</td>
</tr>
<tr>
<td>Fluvoxamine</td>
<td>1,686.1</td>
<td>0.697</td>
<td>Dominated</td>
</tr>
</tbody>
</table>

In order to test the robustness of the model, alternative scenarios and one-way sensitivity analysis were performed; results confirmed those from base-case.

In the Probabilistic Sensitivity Analysis (PSA), the uncertainty in all model inputs was evaluated simultaneously using simulation techniques in which parameters assumed values based on probability functions. PSA confirmed that escitalopram has a probability to be cost-effective higher than one of the other antidepressants.

DISCUSSION

In comparison with the seven antidepressants considered, escitalopram was less costly and more effective in terms of QALYs, dominating all the other pharmacological treatments used in first-line. These results are consistent with other evaluations. [9-13]

A limitation to the study could be the use of data from different sources (meta-analysis and randomized controlled trials) that could provide values considered far from ‘real life’; this choice was due to the lack of data from observational studies. Furthermore, lack of local data regarding some parameters have lead the authors to base estimates on the expert panel opinion. Nevertheless, expert opinion could be considered appropriate when there is little or no published material.

The present study, the first CUA that compares all SSRIs and SNRIs antidepressants approved for MDD treatment in Italy, suggests that the use of escitalopram could result in improved health-related quality of life and probability of sustained remission and health care resource utilization for the Italian health service.

REFERENCES

The objective of this study was to describe the clinical profile of patients with RA treated with biologic agents within the former Italian centers “Antares” where autoimmune diseases are treated.

METHODS

This study analyzed data from patient diaries (PDS), which involved approximately 70 rheumatologists that are regular prescribers of biological treatments for rheumatoid arthritis and were recruited by telephone. The patient diaries were completed via web. The rheumatologists sample was stratified by macro-regions. All diaries about patients affected by Rheumatoid Arthritis, Ankylosing Spondylitis, Juvenile Idiopathic Arthritis, early RA or Psoriatic Arthritis treated with biologic drugs have been analysed.

Statistical analysis has been performed using SAS® software version 9.2.

Qualitative variables have been described using usual statistical methodologies, which are frequencies and percentages. Quantitative variables have been described in terms of mean values, standard deviations, median values, 1° quartile, 3° tertile, minimum and maximum.

RESULTS

A total of 449 diaries have been analysed. The study population consisted of 206 (45.9%) patients with RA, 160 (35.6%) with Psoriatic Arthritis, 61 (13.6%) with Ankylosing Spondylitis, 14 (3.1%) with Juvenile Idiopathic Arthritis and 8 (1.8%) with early RA (Figure 1).

Figure 1. Patients stratified by pathology.

<table>
<thead>
<tr>
<th>Disease</th>
<th>1° Quartile</th>
<th>3° Quartile</th>
<th>Median</th>
<th>38.6%</th>
<th>9.9%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rheumatoid Arthritis (N=206)</td>
<td>1.8%</td>
<td>3.1%</td>
<td>13.6%</td>
<td>35.6%</td>
<td>45.9%</td>
</tr>
<tr>
<td>Early Rheumatoid Arthritis (N=8)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Juvenile Idiopathic Arthritis (N=14)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ankylosing Spondylitis (N=61)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psoriatic Arthritis (N=160)</td>
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</table>

Female gender prevailed, except for Ankylosing Spondylitis and Psoriatic Arthritis groups. The most numerous age group at the visit time was the one that ranged from 50 to 60 years and the major part of patients have had the diagnosis before they were 50 years old.

The major part of the sample had a moderate disease severity and a medium disease progression rapidity at the diagnosis time.

At the visit time, the most prescribed biologic drugs among RA patients were Enbrel 50 and Humira, followed by Orencia, Roactemra, Cimzia and Remicade with a suggested continuous therapeutic scheme.

No substantial differences have emerged from the analysis of quality of life in relation with the time since therapy start: even if in the group of patients treated with a biologic drug since more than 3 months, there’s the highest percentage of subjects with a HAQ value lower than 1, the percentage of patients with a HAQ value comprised between 2 and 3 is still quite elevated (40.0%) (Figure 2).

Figure 2. Patients stratified by time since biologic therapy start and HAQ Index.

The stratification of patients by time since biologic therapy start and DAS28 Index categories has shown that the percentage of patients that are in remission is higher for patients that are assuming the biologic drug for more than 3 months. Anyway, even in this case, the percentages of patients with moderate or elevate disease activity among those treated for more than 3 months is still quite high (respectively 39.7% and 9.9%) (Figure 3).

Figure 3. Patients stratified by time since biologic therapy start and DAS28 Index.

CONCLUSION

The present study has shown that there is a proportion of patients treated with biological therapy for more than three months, as well as an important number of patients who have been treated with more than one biologic drugs, that have a perception of quality of life rather low and / or a disease activity rate rather active suggesting that there is still a type of patient for which new therapeutic options should be evaluated.